



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 17 1999

1442 '99 MAY 18 10:12
Re: Arava™
Docket No. 99E-0118

The Honorable Q. Todd Dickinson
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,284,786 filed by Hoechst Aktiengesellschaft under 35 U.S.C. § 156. The human drug product claimed by the patent is Arava™ (leflunomide), which was assigned new drug application (NDA) No. 20-905.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990).

The NDA was approved on September 10, 1998, which makes the submission of the patent term extension application on November 5, 1998, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Stephen L Nesbitt
Hoechst Marion Roussel, Inc.
P.O. Box 156300
2110 East Galbraith Road
Cincinnati, OH 45215-2367

99E-0118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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Memorandum

Date:

From: Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application
for **AravaTM**

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned human drug product under the Docket Number **99E-0118** stating that this particular patent is eligible for regulatory review.. The Patent Number is **4,284,786**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.